

PATENT APPLN. NO. 10/540,621  
RESPONSE UNDER 37 C.F.R. §1.111

PATENT  
NON-FINAL

IN THE DRAWINGS:

Replace the drawing with the attached Replacement Sheet of Drawings.

REMARKS

Claim 1, directed to the product of the invention, has been canceled. Claim 14, directed to the method of the invention, has been amended. Claims 2-13 have been amended to depend on method claim 14.

Referring to the Action, a replacement sheet of drawings is required. A replacement sheet of drawings is attached to the instant response. In the replacement sheet of drawings, sponge matrix (B) and linear nerve inducing channel (C) are identified by proper labels.

Claims 1 and 3-13 are rejected in the Action under 35 U.S.C. § 102(b) as being anticipated by Doi et al., Patent Application Publication No. US 2002/0161450 A1 ("Doi"). Claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Doi.

These rejections are now moot in view of the cancellation of claim 1 and the amending of claims 2-13 to be dependent on method claim 14.

Claim 14 is rejected in the Action under 35 U.S.C. § 102(b) as being anticipated by Doi or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Doi.

This rejection as it applies to claims 2-14 is respectfully traversed.

Claim 14 has been amended to recite that in the method of using the nerve regeneration-inducing tube of the present invention, the nerve regeneration-inducing tube, which comprises a tubular structure (A) made of a biodegradable material or bioabsorbable material and includes therein a sponge matrix (B) made of a biodegradable material or bioabsorbable material and/or a linear nerve inducing channel (C), and an insertion space for insertion of a nerve end formed at only one end of the tubular structure (A), the method includes the step of adjusting a length of the nerve regeneration-inducing tube according to the length of the injured area of the nerve during an operation, by cutting the end of the nerve regeneration-inducing tube not having the insertion space, i.e., the end devoid of the insertion space, prior to the step of suturing an end of a central nerve inserted into the insertion space with the tubular structure (A).

Doi fails to disclose each of the elements of the method of claim 14 and, more particularly, fails to disclose:

(1) a nerve regeneration-inducing tube comprising a tubular structure (A) made of a biodegradable material or bioabsorbable material including therein a sponge matrix (B) made of a biodegradable material or bioabsorbable material and/or a linear nerve inducing channel (C); and having an insertion space for

insertion of a nerve end formed at one end of the tubular structure (A);

(2) adjusting a length of the nerve regeneration-inducing tube according to the length of the injured area of the nerve during an operation, by cutting only one end of a nerve regeneration-inducing tube not having an insertion space; and

(3) inserting an end of a central nerve into the insertion space for insertion of a nerve end.

More particularly, Doi does not disclose or suggest to a person of ordinary skill in the art a nerve regeneration-inducing tube as recited in claim 14 having a space for insertion of a nerve end formed at only one end of a tubular structure (A). Fig. 1 of Doi, relied on by the Office as disclosing a nerve regeneration-inducing tube having a space for insertion of a nerve end formed at one end of the tubular structure, does not show the actual structure of the instrument for regeneration of Doi. Fig. 1 of Doi is only a schematic illustration that is provided to show the components of the instrument for regeneration.

A person of ordinary skill in the art would understand from a reading of Doi that the instrument for regeneration of Doi does not have an insertion space provided at one end of the structure. This fact is supported, for example, by the description of the method

for making the instrument of Doi as described in Example 1. In Example 1, it is described that a tubular structure is formed by winding collagen fiber around a mandrel and that "[i]n its lumen, 200 collagen fibers having a diameter of 50  $\mu$ m were simultaneously inserted together with the aqueous 5% collagen solution ... ." (Paragraph [0071], lines 8-11). There is no description of an insertion space being formed at one end of the tubular structure or of steps that would result in such an insertion space.

Moreover, it is also clear from the description of the test for tissue regeneration described in Example 1 of Doi that an end of a central nerve is not inserted into an insertion space provided at an end of the instrument for regeneration formed in Example 1. Specifically, Doi describes:

"The rat fibula nerve was cut to make a 10-mm deficit portion. In this site the tubular collagen-made instrument for regeneration of organ previously cut to 10 mm, i.e., the same length as the deficit length, and ... ."

It is clear that the tubular collagen-made instrument for regeneration of Doi which is cut to the same length as a deficit length can not have an insertion space provided at an end thereof and that, therefore, Doi does not disclose a method as recited in claim 14 and the claims dependent thereon, claims 2-13.

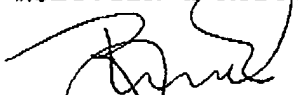
For these reasons, removal of the 35 U.S.C. § 102(b) and alternative 35 U.S.C. § 103(a) rejections based on Doi and an allowance of claims 2-14 are in order and are respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated October 29, 2008.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,  
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Attachment: Replacement sheet of drawings